

U.S. Patent Application Serial No. 09/654,276
Reply to Office Action of December 8, 2004

REMARKS

Applicants respectfully request entry of the amendment and reconsideration of the claims. Claims 16, 19, and 23 have been amended to further clarify the claimed invention. Applicants assert that no new matter has been added. Claims 1-3, 5, 6, 9, 10, and 16-24 are currently pending. The Examiner indicated claims 1-3, 5, 6, 9, 10, and 22 are allowable.

Rejection under 35 U.S.C. § 103

Claims 16-21, 23, and 24 were rejected under 35 U.S.C. § 103(a) as unpatentable over U.S. Patent No. 6,099,832 (Mickle et al.) in view of WO97/44070 (Shapiro et al.). The Office Action alleges it would have been obvious to substitute the alginate scaffolds disclosed in Shapiro et al. for the collagen scaffolds taught by Mickle et al. Applicants respectfully traverse this rejection.

Applicants note that claim 18 is a method claim that depends from claim 2. The Examiner has indicated that claim 2 is allowable. Accordingly, withdrawal of this aspect of the rejection is respectfully requested.

The Patent Office bears the initial burden of factually supporting any *prima facie* conclusion of obviousness. MPEP § 2142. Three criteria must be to establish a *prima facie* case of obviousness. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine the teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference must teach or suggest all the claim limitations. In re Vaeck, 947 F.2d 488 (Fed. Cir. 1991). One or more of the three criteria has not been established.

Alginates do not promote adhesion of cells (see, for example, Rowley et al., 1999, Biomaterials, 20:45-53 (copy enclosed)). The non-adhesive property of the alginate matrices enables the fast spreading of cells from the matrix into the host tissue. The cells, and not the alginate matrix, interact with the extracellular matrix (ECM). In contrast, collagen contains an

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RGD domain that is adhesive to cells and the extracellular matrix (ECM). Cells adhere to collagen-based matrices and spread out. In addition, collagen-based matrices, unlike alginate-based matrices, adhere to the ECM.

One of skill in the art could not predict the outcome of a cardiac biograft comprising an alginate scaffold in view of the collagen-based cardiac biograft disclosed by Mickle et al. The adhesive properties of collagen-based matrices result in a completely different product. Moreover, one of skill in the art would not have been motivated to combine Mickle et al. and Shapiro et al. as the ECM binding properties of collagen-based biografts and the cell adherence properties of collagen-based biografts are substantially different from those of alginate-based scaffolds.

Accordingly, Applicants assert that the Office Action has failed to establish a *prima facie* case of obviousness and the claims patentably distinguish over the combination of references. Withdrawal of the rejection is respectfully requested.

Conclusion

In view of the above amendments and remarks, Applicants respectfully request a Notice of Allowance. If the Examiner believes a telephone conference would advance the prosecution of this application, the Examiner is invited to telephone the undersigned at the below-listed telephone number.


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PATENT TRADEMARK OFFICE

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Respectfully submitted,

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